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Appl. No. : 10/669,951
Filed : September 24, 2003

REMARKS

The claim amendments and remarks herein are responsive to the Office Action dated December 14, 2006. Claims 1-25 and 27-38 are pending. Applicant has canceled Claim 26 without prejudice.

Claim Rejections¹

Rejection Under 35 U.S.C. § 102

The Examiner rejected Claims 1-11, 16, 18-25, and 27-38 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 6,174,311 to Branch et al.

Branch discloses several instruments to prepare an implant, prepare the implant site, and insert the prepared implant. Branch's instruments are individual and separate instruments. For example, prior to the introduction of the rotational cutting handtool in FIG 34, Branch discloses an implant and implant holder (FIG 1-24) a chisel hand tool (FIG 25), a shaver handtool, a slap hammer (FIG 27), a nerve retractor (FIGS 29-31), a round scraper (FIG 32), and a plane scraper (FIG 33).

By contrast, Applicant's Claims 1-11, 16, 18-25, and 27-38 are directed to a **single implantable stabilizing device** that is used for preparing the implantation site, cutting, and harvesting bone. Unlike Branch's multiple devices, Applicant's device as recited in these claims is a single multi-functional implantable device.

FIG 34 of Branch to which the Examiner referred, merely discloses a **site preparation tool**, and not an implant. The discussion of FIG 34 in Branch's specification provides, in its entirety:

As shown in FIG. 34, there is also provided in accordance with the present invention rotatable cutter 430. Cutter 430 includes handle 432, shaft 434, and cutter head 436. Cutter head 436 includes first cutting arm 437 and second arm 439. First cutting arm 437 and second cutting arm 439 are spaced apart and define a cavity 448 therebetween for receipt of cutting debris. First cutting arm 437 includes at least two cutting blades. For example, FIG. 34a depicts cutting arm 437 having a first cutting blade 438 and opposite second cutting blade 440. First and second cutting blades extend longitudinally and are positioned to lie parallel to the longitudinal axis of rotatable cutter 430. Similarly, second cutting arm 439 is provided with a first cutting blade 442 and a second cutting blade 443.

¹ Applicant's arguments that the pending claims are patentable over the art cited herein is not an admission that the cited art qualifies as prior art. Applicant expressly reserves the right to assert that the cited art is not prior art in the future should the need arise.

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Rotatable cutter 430 is provided for use in a disc space to cut adjacent endplates of adjacent vertebrae by a twisting the cutter. As with other instruments, the cutting head includes index marks 441 to indicate the depth the rotatable cutter is inserted into tissue.

Because Branch does not teach or suggest the unitary implantable device recited in Applicant's claims, Branch does not anticipate Applicant's claims.

Moreover, in addition to Branch's failure to teach Applicant's invention as recited in Claims 1-11, 16, 18-25, and 27-38, Branch also fails to teach "a leading edge for straight cutting as the implant is advanced between adjacent vertebrae." Branch only teaches cutting arms (forming a cavity for bone debris) and opposing horizontal cutting blades for rotational cutting (not straight cutting). This absence in Branch's disclosure is consistent with Branch's use of multiple tools. Because Branch uses separate implantation and site preparation tools, it is not necessary or logical that Branch's implant would have a chisel or lead edge for straight cutting. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-11, 16, 18-25, and 27-38 under 35 U.S.C. § 102(b).

Claims 27-38

The Examiner stated that Claims 27-38 were anticipated by Branch because the method steps would have been inherently carried out in the operation of Branch's device.

Claims 27-38 are patentable for the reasons discussed above. Moreover, even assuming *arguendo* that the claimed method steps may occur in the operation of the cited art device (which they do not), this alone is entirely insufficient to establish inherency. MPEP 2112 (IV) emphasizes:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not

Appl. No. : 10/669,951
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sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)....²

MPEP 2112 (IV) also emphasizes that the BPAI requires the examiner to show that any allegedly "inherent" features necessarily occur in the cited art:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)...

There is simply no evidence to show that the method steps recited in Applicant's Claims 27-38 are always and necessarily present in the operation of the devices described in the cited art. Accordingly, the Examiner's rejection cannot be maintained. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 27-38 under 35 U.S.C. § 102(b).

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 12-15, and 17 under 35 U.S.C. § 103(a) as being obvious over Branch in view of US Patent No. 3,527,841 to Wicker et al.

Because Claims 12-15, and 17 depend from an allowable base claim (namely, Claim 1), these claims are allowable over the cited art. Moreover, Claims 12-15, and 17 recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 12-15, and 17 under 35 U.S.C. § 103(a).

² Emphasis added.

Appl. No. : 10/669,951
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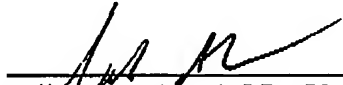
Applicant respectfully asserts that the present application is fully in condition for allowance. *If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below.* Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 8, 2006

By: _____


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